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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/803,512

03/18/2004

Guy Rome

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34284

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09/28/2010

Rutan & Tucker, LLP.

611 ANTON BLVD

SUITE 1400

COSTA MESA, CA 92626

EXAMINER

VU, QUYNH-NHU HOANG

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MAIL DATE

DELIVERY MODE

09/28/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/803,512	Applicant(s) ROME, GUY	
	Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-47 is/are pending in the application.
- 4a) Of the above claim(s) 34-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-33 and 40-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>08/17/10</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION***Response to Amendment***

The amendment filed on 08/24/10 has been entered in the case. Claims 30-33, 40-47 are pending for examination, claims 34-39 have been withdrawn and claims 1-29 have been cancelled.

Drawings

The drawings 7A-C (elected Species) are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the limitation "*a distal end of connector attached to a proximal end of catheter*" and limitation "an engagement feature" of claim 1 must be shown in Figs. 7A-C or the feature(s) canceled from the claim(s). And the combination of limitation "*a distal end of connector attached to a proximal end of catheter*" of claim 1 and the limitation "*the engagement feature comprise an O-ring; and wherein a wall defining the proximal portion the passageway proximal of the O-ring is tapered*" of claim 3 must be shown in Figs. 7A-C or the feature(s) canceled from the claim(s).

the limitation "the engagement feature includes a projection into the passageway; wherein the projection has a reduced diameter relative to an inside diameter of the passageway on a proximal side and a distal side of the projection" of claims 46-47 must be shown in Figs. 7A-C or the feature(s) canceled from the claim(s).

Beside that, a built-in valve element should be named in Figs. 7A-C.

No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the

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filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear to Examiner that which element is considering as an engagement feature configured to connect an end of an instrument to the connector"?

For examining purpose, the Examiner assumes that an engagement feature element is as something to hold/connect with an instrument.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

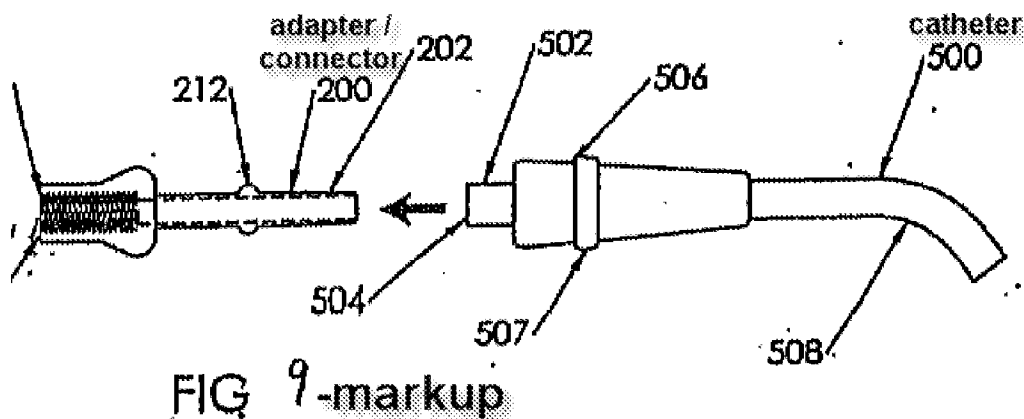
Claims 30-33, 40-41, 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Canaud et al. (US 2004/0193119).

Regarding claims 30 and 44-45, Canaud discloses a catheter assembly in Fig. 9 comprising: a catheter 500 including at least one lumen; a connector/adaptor 200 (Figs. 2 and 9) or 270 (Fig. 3, note that the adaptor 270 is generally includes similar features of the adaptor 200 shown in Fig. 2, see para [0042]) including a distal end 202 attached to a proximal end 502 of the catheter and a passageway 206 (Fig. 2) or 278 (Fig. 3) in fluid communication with the at least one lumen 504, see Figs. 9-10; a proximal portion of the passageway including an engagement feature (i.e. element 208 having a thread connection

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214 (Fig. 2), 286 (Fig. 3)) configured to connect an end of an instrument (i.e. tulener 300 or a port 400, see Fig. 1) to the connector 200 or 270; a distal portion of the passageway 278 including a valve 272 longitudinal fixed (firmly in position) with respect to the connector 270. Canaud further discloses that other types of valve (i.e. duck valve or slit valve) may be used in the adapter 270, see para [0043], therefore, one of examples of the type of duckbill valve 424 in Fig. 7 can be used in the adapted 270; wherein the valve having a closed proximal end with a slit (as well-known in the duckbill valve art) and open distal end, (see valve 424 of Fig. 7) and the proximal end of valve 272 distal of the engagement feature 286.

Regarding the limitation "built-in" of valve element, it would have been obvious to one having ordinary skill in the art at the time the invention was made to obtain the built-in valve, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art.



Regarding claim 31, note that the valve includes a wall defining a lumen from the proximal end to the distal end, the wall configured to or (adapted to/capable of) to guide a proximal end of a guide-wire from the valve distal end through the slit in the valve proximal end.

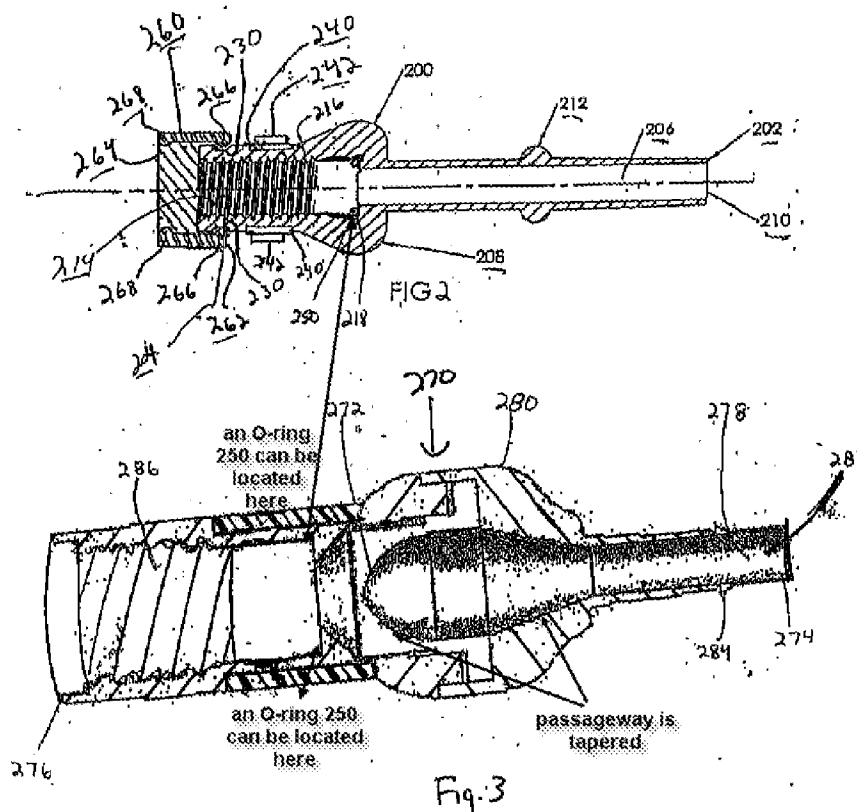
Regarding claim 32, Canaud discloses the claimed invention except for that the connector comprise a material having a hardness in the range of about 90 Shore A to about 90 Shore D, and

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wherein the valve comprises a material having a hardness in the range of about 40 Shore A to about 60 Shore A.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the material of connector and valve as listed above, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claim 33, note that Canaud discloses the engagement feature 208 of adapter 200 in Fig. 2 comprises an O-ring 250 to help facilitate sealing between the adapter and port 400 or the tunneler 300, (see para [0039]) while the engagement feature of adapter 270 does not include an O-ring, however, one skill in the art would recognize that the O-ring 250 can be located in the adapter 270 for the purpose of helping facilitate sealing between the adapter and port 400 or the tunneler 300. Note that, a wall defining the proximal portion of the passageway proximal of the O-ring is tapered, see Fig. 3 below.



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Regarding claim 40, note that Canaud also discloses the connector 270 includes a tapered outer surface (at portion of element 280 in Fig. 3) at a proximal end thereof.

Regarding claim 41, note that Canaud discloses in Fig. 1 that a syringe adaptor 400 including a distal end 406 (Fig. 7) inserts into either adaptor 200 of Figs. 1-2 or adaptor 270 of Fig. 3; and a proximal opening 418 (Fig. 7) opening to receive a male luer, see para [0066]. Meanwhile, the claimed invention requires that the distal end of syringe adaptor configured to slide over the tapered proximal end of the connector.

It has been held that the recitation that the distal end of connector is “configured to/adapted to/capable of” performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In this case, one skill in the art would recognize that instead of engagement between the syringe adaptor 400 and the connector/the adaptor 200 or 270 by thread connection, there is other way well-known in the art that engagement between two elements (i.e. syringe adaptor and connector) by friction fit; wherein the distal end of syringe adaptor either slide over or slid into the proximal end of the connector is considered as rearranging parts or constructing a formerly structure in various elements of an invention involves only routine skill in the art.

Regarding claim 43, note that the valve is a duckbill valve therefore, it is well-known in the art that the duckbill valve comprise a slit and the slit is inherently opened by insertion of a medical device through the valve.

Regarding claim 46, the engagement feature includes a projection (thread 286) into the passageway.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Canaud et al. (US 2004/0193119) in view of Wilson et al. (US 6,921,396).

Canaud discloses the invention substantially as claimed invention. Canaud also discloses that the projection (thread 286) has a reduced diameter relative to an inside diameter of the passageway on a proximal side but not at distal said of the projection as recited in claim 47.

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Wilson discloses a connector 12 comprises an engagement feature 32 (Fig. 6) or 52 (Fig. 7) includes a projection 32 or 52 into a passageway 22; wherein the projection has a reduced diameter relative to an inside diameter of the passageway on a proximal side and a distal side of the projection. Noted that the engagement feature/coupling portion 32/24 is configured for securing be mating engagement with other medical device.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Wilson with a projection, as taught by Wilson, in order to secure the mating engagement with other medical device.

Claims 30, 40, 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (US 6,921,396) in view of either Krug (US 4,502,502) or Duncan et al. (US 4,535,818).

Regarding claims 30, 43-45, Wilson discloses a catheter assembly in Figs. 6-8 comprising: a catheter 14 or 16 including at least one lumen; a connector 12 including a distal end 26 attached to a proximal end of the catheter and a passageway 22 in fluid communication with the at least one lumen 28, a proximal portion of the passageway including an engagement feature 32, 52 configured to connect an end of an instrument (i.e. trocar 40 or syringe 60) to the connector.

Wilson does not disclose a built-in valve as recited in claim 1.

Krug discloses a connector 10 shown in Figs. 1-2 comprising: a valve 18 longitudinal fixed with respect to the connector having a closed proximal end with a slit and an open distal end 20 for controlling the flowing of liquids.

Duncan discloses a connector 42a shown in Figs. 7-8 comprising: a valve 52a longitudinal fixed with respect to the connector having a closed proximal end with a slit 56a and an open distal end 62a for controlling the flowing of liquids.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Wilson with a valve provided in the connector, as taught by either Krug or Duncan, in order to control the flowing of liquids.

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With regarding the limitation "built-in" of valve element, it would have been obvious to one having ordinary skill in the art at the time the invention was made to obtain the built-in valve, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art.

Regarding claim 40, note that Wilson further discloses that a tunneler 40, wherein the engagement feature 32, 52 (see Figs. 6-7) engages a tip 42, 49 of the tunneler upon insertion of the tunneler tip into the proximal portion of the passageway 22.

Regarding claims 46-47, note that Wilson discloses the engagement feature 32, 52 includes a projection 32, 52 into the passageway; wherein the projection has a reduced diameter to an inside diameter of the passageway on the proximal side and a distal side of the projection, see Figs. 6-7.

Response to Arguments

Applicant's arguments with respect to claims 30-33, 40-47 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

/Quynh-Nhu H. Vu/
Examiner of Art Unit 3763